DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 21, 2015

Cooper Surgical Inc.
% Tim Lohnes
Senior Regulatory Consultant
Orchid Design
80 Shelton Technology Center
Shelton, CT 06484

Re: K143650
Trade/Device Name: CooperSurgical Advincula Delineator™ Uterine Manipulator
Regulation Number: 21 CFR 884.1640
Regulation Name: Culdoscope and accessories
Regulatory Class: Class II
Product Code: HEW
Dated: June 16, 2015
Received: June 18, 2015

Dear Mr. Lohnes,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin Fisher, PhD.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K143650

Device Name
CooperSurgical Advincula Delineator™ Uterine Manipulator

Indications for Use *(Describe)*
The CooperSurgical Advincula Delineator™ Uterine Manipulator is indicated to provide delineation of the vaginal fornices and maintain pneumoperitoneum as a uterine manipulator during Total Laparoscopic Hysterectomy (TLH), Laparoscopic Assisted Vaginal Hysterectomy (LAVH) and/or Laparoscopic Supra-Cervical Hysterectomy (LSH).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**07. 510(K) SUMMARY**:

510(k) Summary of Safety and Effectiveness, (21 CFR 807.92):

| | |
|---|---|
| Submitter: | Cooper Surgical Inc.,<br>95 Corporate Drive,<br>Trumbull, CT 06611 |
| Contact Person: | Tim M. Lohnes<br>Senior Regulatory Consultant,<br>Orchid Design<br>Phone: (203) 922 0105<br>Fax: (203) 922 0130<br>tim.lohnes@orchid-ortho.com |
| Date Prepared: | December 15, 2014 |
| Name of Device:: | CooperSurgical Advincula Delineator™<br>Uterine Manipulator |
| Common/Usual Name: | Cannula, manipulator/injector, uterine |
| Classification Name: | 884.1640, Culdoscope and accessories |
| Device Class: | Class II |
| Product Code: | HEW |
| Predicate Device(s): | Cooper Surgical Koh Colpotomizer System, K954311 |

Device Description;

The CooperSurgical Advincula Delineator™ Uterine Manipulator is a single use device, supplied sterile to the end user. It includes a cup shaped sliding colpo-pneumo occluder used to delineate the vaginal fornices, providing an anatomical marker to facilitate resection of the uterus, and a balloon to occlude the vaginal vault to maintain pneumoperitoneum during uterine resection.

Intended Use:

The CooperSurgical Advincula Delineator ™Uterine Manipulator is indicated to provide delineation of the vaginal fornices and maintain pneumoperitoneum as a uterine manipulator during Total Laparoscopic Hysterectomy (TLH), Laparoscopic Assisted Vaginal Hysterectomy (LAVH) and/or Laparoscopic Supra-Cervical Hysterectomy (LSH).

Comparison of Technological Characteristics to the Predicate Device:

| Attribute | Cooper Surgical Advincula Delineator™ Uterine Manipulator (subject) | Cooper Surgical Koh Colpotomizer System, K954311 | Determination |
|---|---|---|---|
| Body Contact Type | External communicating, tissue, ≤ 24 hours | External communicating, tissue, ≤ 24 hours | Substantially Equivalent |
| Material(s) | Stainless steel, silicone, various plastics, adhesives and inks. | Stainless steel, silicone, various plastics, adhesives and inks. | Substantially Equivalent |
| Environment | Operating room | Operating room | Substantially Equivalent |
| Vaginal Occlusion (Pneumoperitoneum) | Occluder balloon with inflation capacity of 60-120cc | Occluder balloon with inflation capacity of 90-120cc | Different |
| Indications for Use | The CooperSurgical Advincula Delineator™ Uterine Manipulator is indicated to provide delineation of the vaginal fornices and maintain pneumoperitoneum as a uterine manipulator during Total Laparoscopic Hysterectomy (TLH), Laparoscopic Assisted Vaginal Hysterectomy (LAVH) and/or Laparoscopic Supra Cervical Hysterectomy (LAH). | The Koh Colpotomizer System is indicated for use in all laparoscopic procedures where the use of a uterine manipulator is appropriate and the surgeon intends to remove or access intraperitoneal tissue through the vagina by use of a colpotomy or culdotomy incision. | Substantially Equivalent |
| Biocompatibility | The patient contacting components of the Advincula Delineator™ Uterine Manipulator have been evaluated for biocompatibility as appropriate for their contact classification (ext. communicating, tissue/bone/dentin, ≤ 24 hours. | The patient contacting components of the Koh Colpotomizer System have been evaluated for biocompatibility as appropriate for their contact classification (ext. communicating, tissue/bone/dentin, ≤ 24 hours. | Substantially Equivalent |

| | | | |
|---|---|---|---|
| Packaging | The Advincula Delineator™ Uterine Manipulator is packaged in a 16 Mil Flexible Blister pouch with a heat-sealed 1073B Tyvek lid, packed 3 to a carton. | The Koh-Efficient device is packaged in a .035" PETG Blister; heat-sealed 1073 Tyvek lid, packaged 6 to a chipboard carton. | Substantially Equivalent |
| Stability/Shelf Life | The Advincula Delineator™ Uterine Manipulator is sterilized by ETO to a Assurance Level (SAL) of $10^{-6}$, with an initial shelf life of 1 year. | The sterile components of the Koh-Effecent System device are sterilized by ETO gas to a Assurance Level (SAL) of $10^{-6}$, with a shelf life of 2 years. | Substantially Equivalent |

The basis of substantial equivalence of the CooperSurgical Advincula Delineator™ Uterine Manipulator is the similarities in materials, design, function, performance, sterilization, and indications for use in comparison to the predicate device. The primary technological difference between the subject and predicate devices is the inflation capacity of the vaginal occluder balloon. However, this minor difference does not raise different questions of safety or effectiveness as the maximum inflation pressure is the same for both the subject and predicate devices. In addition, burst volume testing was conducted to demonstrate that the difference in inflation pressure does not affect the safety and effectiveness of the subject device.

Performance Data:

The Cooper Surgical Advincula Delineator™ Uterine Manipulator was tested in comparison to the predicate Cooper Surgical Koh Colpotomizer System K954311, with regards to;

1) Distal & proximal balloon burst volume
2) Distal & proximal balloon leakage
3) Distal & proximal balloon fill tube tensile strength

The Cooper Surgical Advincula Delineator™ Uterine Manipulator was also tested in regards to bending, compression, and tension forces applied to the tube, as well as the security of the sliding colpo-pneumo occluder when locked.

Clinical testing was not required to support the conclusion of substantial equivalence.

Conclusion:

The substantial equivalence of the CooperSurgical Advincula Delineator™ Uterine Manipulator has been established by demonstrating the similarities in design, materials, function, performance, and Intended Use are equivalent to the previously cleared Cooper Surgical Koh Colpotomizer System, K954311.